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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,408	12/26/2001	Larry Caldwell	CALD-005	3760

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
1615	7

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	10/029,408	CALDWELL ET AL.
Examiner	Art Unit	
Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-23 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4, 5</u> .	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus (U.S. Patent No. 6,399,093 B1) in view of Crandall (U.S. Patent Application Publication No. US 2002/0164389 A1) and Biedermann *et al.* (U.S. Patent No. 5,980,921)

The Petrus patent teaches compositions for the treatment of musculoskeletal disorders, which includes carpal tunnel syndrome (See Abstract; and Column 1, Lines 26-44). Among the suitable active ingredients disclosed are non-steroidal anti-inflammatory agents, such as indomethacin, diclofenac, ibuprofen and ketoprofen (See Column 4, Table 1). The disclosed compositions may be formulated into various dosage forms, including creams and films (See Column 3, Lines 18-25). Such compositions are suitable for treating humans afflicted with musculoskeletal disorders (See Column 13, Examples 3 and 4).

The Petrus patent does not explicitly disclose the treatment of carpal tunnel syndrome by applying a topical formulation to a palmar dermal surface proximal to the carpal tunnel.

The Crandall publication discloses methods for the treatment of carpal tunnel syndrome (See Abstract). Treatment is effected, in one embodiment, by the use of a topical formulation,

applied to the wrist of a subject in need of treatment (See Sections [0034] and [0046]). Suitable dosage forms for topical application include creams and pads (See Claims 1, 2, and 4).

The Biedermann *et al.* patent is used here merely as a teaching reference to point out that diclofenac and indomethacin are known in the art as acetic acid derivatives (See Column 11, Line 66 to Column 12, Line 3).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. One of ordinary skill would be motivated to use the compositions of the Petrus patent in treating carpal tunnel syndrome by applying the disclosed compositions to the wrist of a subject in need of treatment, as disclosed in Crandall. It is the position of the examiner that one of ordinary skill would be so motivated to use any topical treatment disclosed to be effective in treating carpal tunnel syndrome in the manner described in Crandall, with a reasonable expectation of success in the amelioration of pain associated with the disorder. It is the position of the examiner that topical forms disclosed in the prior art such as films and pads sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petrus in view of Crandall, Biedermann *et al.*, and Shudo *et al.* (U.S. Patent Application Publication No. US 2002/0176886 A1)

The relevant portions of Petrus, Crandall, and Biedermann *et al.* are detailed in the above rejection of Claims 1-18 under 35 U.S.C. 103(a).

Petrus, Crandall, and Biedermann *et al.* do not provide for kits containing a topical formulation and instructions for use according to a claimed method of treatment.

The Shudo *et al.* publication discloses kits comprising topical patch formulations as well as instructions for use, which may be printed or embodied in the form of electronic media (See Section [0044]). This publication is relied upon primarily as a teaching reference to show that it is known in the art that in certain instances, it may be desirable to provide kits that provide a topical formulation as well as instructions for use in accordance with a disclosed method of treatment.

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of the prior art into the objects of the instantly claimed invention. One of ordinary skill would be motivated to use the compositions of the Petrus patent in treating carpal tunnel syndrome by applying the disclosed compositions to the wrist of a subject in need of treatment, as disclosed in Crandall. It is the position of the examiner that one of ordinary skill would be so motivated to use any topical treatment disclosed to be effective in treating carpal tunnel syndrome in the manner described in Crandall, with a reasonable expectation of success in the amelioration of pain associated with the disorder. It is the position of the examiner that topical forms disclosed in the prior art such as films and pads sufficiently read on the instantly claimed invention so as to make the use of patches in treatment obvious to one of ordinary skill in the art. The provision of topical dosage forms in a kit that further comprises instructions for use in accordance with the instantly claimed methods of treatment of carpal tunnel syndrome is also considered by the examiner to be obvious to one of ordinary skill in the art. It is further the position of the examiner that the provision of other

topical dosage forms, such as creams, in such a kit would also be obvious to one of ordinary skill in the art. Thus, the instantly claimed invention is *prima facie* obvious.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sjo  
July 14, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
